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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/539,934 | 02/17/2006 | Stephen May | 0380-CP6298426 | 1122 |
| 110 7590 09/17/2008 DANN, DORFMAN, HERRELL & SKILLMAN | | | EXAMINER | |
| 1601 MARKET STREET | | | BADR, HAMID R | |
| SUITE 2400 PHILADELPHIA, PA 19103-2307 | | ART UNIT | PAPER NUMBER | |
| | | | 1794 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 09/17/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|------------------------------------|-----------------------|--|--|--|--|
| | 10/539,934 | MAY ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | HAMID R. BADR | 1794 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | | | | | | |
| | -· action is non-final. | | | | | |
| <i>;</i> — | | | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| | | 0 0.0.2.0. | | | | |
| Disposition of Claims | | | | | | |
| 4) ☐ Claim(s) 8-19 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 8-19 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date | | | | | | |
| | | | | | | |

Application/Control Number: 10/539,934 Page 2

Art Unit: 1794

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 8-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 3. Claims 8 and 12 are indefinite for "tocopherol" and/or "tocotrienol". It is unclear how these compounds function as blood cholesterol lowering agents. It is not clear what the applicants regard as the invention.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 8-12, 14, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kneeland et al. (US 3,011,893; hereinafter R1) in view of Piironen et al. (2000, Review: Plant sterols: biosynthesis, biological function and their importance to human nutrition; hereinafter R2) and Kubota et al. (US 3,873,729; hereinafter R3)
- 6. R1 discloses a process for making a novel filled milk product; a method for making from skim milk, vegetable oil and water (Col. 2, lines 57-59).

Application/Control Number: 10/539,934

Art Unit: 1794

7. R1 teaches mixing skim milk and vegetable oil and homogenizing the mixture to create the filled milk.

Page 3

- 8. While R1 teaches using vegetable oils, R1 is silent regarding the phytosterol content of vegetable oils as well as cheese making process or product.
- 9. R2 reviews the chemistry and biochemistry of phytosterols and clearly states that the sterols have the capacity to lower plasma cholesterol and low density lipoprotein (LDL) cholesterol. (Abstract).
- 10. R2 gives a detailed description of the plant sterols (phytosterols) and their natural sources. R2 discloses that germ and bran fractions are the best sources of plant sterols. The total sterol contents determined for wheat germ, wheat bran and oat bran were 42.38, 44.92 and 9.43 mg per gram of lipids (page 948, col. 2, second paragraph).
- 11. R2 is silent regarding the cheese making process and cheese product containing phytosterols.
- 12. R3 discloses the preparation of a cheese like fermented food from an oil in water type emulsion in an aqueous solution containing milk solids. R3 teaches that after pasteurizing the emulsion, a starter is added to the emulsion for fermentation which would form curd and whey. After the completion of the fermentation and acid formation the liquid emulsion is coagulated by rennet, cutting (whey separation), cooking (whey separation), pressing, salting and aging, the cheese like food is obtained. (Col. 2, lines 50-68).

Application/Control Number: 10/539,934

Art Unit: 1794

13. Assuming that a regular cheese contains about 30% fat, and if this fat is provided by wheat germ oil containing about 42 mg sterols per g of lipid (see paragraph 11 above), the cheese like product will have about 1.26% sterol.

Page 4

- 14. R1 and R2 clearly disclose that a filled milk can be made containing vegetable oils. R3 teaches that a cheese like product can be obtained using the filled milk. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to prepare a filled milk as taught by R1 using a vegetable oil containing high concentration of phytosterols, such as wheat germ oil, as taught by R2, and finally prepare a cheese like product as taught by R3. One would do so to prepare a product having texture and flavor of regular cheese while being low in cholesterol (because of skim milk) meanwhile providing blood cholesterol lowering phytosterols. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in making such a cheese product.
- 15. Claims 13, 15, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over R1, R2 and R3 as applied above, further in view of Blernoth et al. (GB 2,214,776; hereinafter R4).
- 16. R1 teaches that the milk, water and vegetable oil are homogenized to obtain the final product. R1, R2 and R3 are silent regarding the injection technique of incorporating the fat material into the aqueous mixture.

17. R4 discloses a process for the production of reduced saturated fat cheese using non-dairy fats by combining a fatty composition with an aqueous composition so as to obtain a filled milk (Abstract).

- 18. R4 teaches of mixing the fatty composition and the aqueous phase by stirring at relatively high speed, or by combining both compositions and passing through a static mixer or a pressure valve, or injecting one composition into the other at a pressure difference of at least 60 atmospheres. (Page 5, lines 31-38).
- 19. Therefore, it would have been obvious to one of ordinary skill in the art to inject the oil into the aqueous stream for dispersing the oil in the aqueous phase for effective mixing. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in dispersing the oil into the aqueous phase.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/539,934 Page 6

Art Unit: 1794

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr Examiner Art Unit 1794

/Callie E. Shosho/ Supervisory Patent Examiner, Art Unit 1794